

## REMARKS

Claims 1-20 and 25-34 are pending, claims 21-24 having been canceled by Preliminary Amendment.

Claims 1-13 and 20 were previously withdrawn as being drawn to non elected subject matter. Therefore, claims 14-19 and 25-34 are under examination as to the elected species.

Claims 1-34 have been canceled herein without prejudice to their inclusion in a subsequent divisional or continuation application.

New claims 35-38 have been added, but merely include subject matter from the canceled claims.

No new subject matter has been added by way of the amendments described herein.

### Response to Claim Objections

Several claims were objected to for reasons of formality. Those claims have been canceled herein, therefore the Objections as to those claims are now moot and Applicants request that the Objections be withdrawn. Applicants submit that the newly added claims are free from the informalities of the canceled claims.

### Election/Restriction-

Examiner affirmed that compound 103833 was elected as the species.

Examiner suggested that a claim be added drawn solely to the above elected compound 103833. In amending the claims, Applicants now recite only compound 103833 and analogs and derivatives thereof, and in fact only recite its use in inhibiting HIV replication.

### Response to Rejection under 35 U.S.C. § 112, first paragraph, written description

Claims 14, 16-18 and 27 stand rejected as allegedly lacking adequate written description. Although not necessarily agreeing with the reasoning of the Examiner, all claims as to the method of identifying compounds that inhibit HIV replication and methods for treating HIV or for administering a compound of the invention have been canceled. In fact, all the pending claims have been canceled and new claims 35-38 have been added.

Additionally, New claims 35-38 recite “a method of inhibiting HIV replication” using compound 103833 and analogs and derivatives thereof, all of which are exemplified in the application as filed and all of which were tested for HIV replication-inhibiting activity. Applicants submit that the newly added claims, which merely incorporate matter from the canceled claims, satisfy the Written Description requirement.

Regarding the analogs and derivatives of 103833, Applicants point out that many of those disclosed have excellent HIV replication and REV function inhibiting activity. For Example, it can be seen in Table 8 that compounds 311, 314, 318, 320, 321, 323, 324, 325, 326, 327, 328, 329, 334, 336, and 339 have activity which includes an IC<sub>50</sub> less than 1  $\mu$ M (the IC<sub>50</sub> shown for 103833 is 0.4  $\mu$ M- Table 6), or their IC<sub>50</sub> is <3  $\mu$ M and their TC<sub>50</sub> is >37.6  $\mu$ M . This latter category is included because the compounds with lower toxicity can also be useful (see Table 8). It should be noted that compound 328 of that list is a slight exception because its values are extremely close to these limits (TC<sub>50</sub> is exactly 37.0  $\mu$ M; is IC<sub>50</sub> is 1.06  $\mu$ M).

Regarding inhibiting REV function, Tables 1 and 4 show that REV function is inhibited. The U1 cell assay used in the specification utilizes an integrated provirus in the cells, which requires REV function for particle formation. For example, when the mRNA for luciferase is trafficked down the rev-pathway it is inhibited by 103833, but not in the control. The U1 cell assay measures the latter part of the HIV lifecycle exclusively, which is where REV acts (see Tables 6 and 8).

For these reasons, Applicants submit that the rejections are now moot and request that they be withdrawn and further submit that the new claims satisfy the written description requirement, because all compounds recited in independent claim 35 and its dependent claims are disclosed in the specification as is HIV replication-inhibiting activity for the claimed compounds.

Response to Rejection under 35 U.S.C. § 112, first paragraph, enablement

Claims 14-19 and 25-34 stand rejected as allegedly lacking enablement. As described above, these claims have been canceled herein and therefore these rejections are now moot. Applicants request that these rejections be withdrawn.

As described above new claims 35-38 recite a method of inhibiting HIV replication using compound 103833 and derivatives and analogs thereof, all of which are disclosed in the specification. Dependent claim 38 specifically recites the use of only compound 103833 to inhibit HIV replication. The claims no longer recite methods of treatment or administering compounds identified by methods of the invention or methods of identifying useful compounds.

Applicants submit that new claims 35-38 satisfy the enablement requirements.

Conclusion

The claimed invention, claims 35-38, is believed to be patentable and applicants request passage of the application to issuance.

The Examiner is invited to contact the Applicants' attorney to discuss any matter concerning this application.

Please charge any excess fees due and credit any overpayment to Charge Account No. 50-0423.

Respectfully submitted,

March 30, 2010



Rodney L. Sparks, In-House Patent Counsel  
University of Virginia Patent Foundation  
250 West Main Street, Suite 300  
Charlottesville, VA 22902  
Telephone: (434) 243-6103  
Fax: (434) 924-2493